K121838

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Section 4: 510(k) Summary

510(k) Owner:

JUL 11 2012

Liebel-Flarsheim Company LLC
2111 East Galbraith Rd.
Cincinnati, OH 45237
Establishment Number: 1518293

Contact:	Mr. Craig Buehler
Title:	Regulatory Affairs Specialist
Telephone:	(314) 654-3188
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Date Prepared:	26 March 2012

Device:

Trade Name:	Liebel-Flarsheim Direct Digital Imaging System
Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1650
Device Class:	Class II
Product Code:	MQB

Predicate Devices:

Hydra Vision Urological X-Ray System (K943581)
UROSKOP Omnia (K101491)
Nexus DRF Digital X-ray Imaging System (K103416)

Device Description:

The Liebel-Flarsheim Direct Digital Imaging System is a radiographic and fluoroscopy examination table with the X-ray tube over the table and the detector underneath the patient table. The table top can be moved longitudinally and laterally as well as vertically. The imaging system and table top can be rotated in the Trendelenburg and reverse-Trendelenburg positions. The system is a modified version of the Hydra Vision Urological X-Ray System (marketed as Hydra Vision Plus DR System). The modification features a multipurpose (radiography and fluoroscopy) solid state digital detector in place of the Image Intensifier and CCD camera for image acquisition. The table design remains unchanged.

Indication for Use:

The Liebel-Flarsheim Direct Digital Imaging System is a solid state detector X-ray system that facilitates digital radiologic and/or fluoroscopic procedures requiring a beam of diagnostic quality radiation and a flat imaging table primarily for urological applications such as functional x-ray diagnostics, endourology and minimal invasive urology/surgery. The system may be used for urological, gastroenterological, and gynecological treatment, planning and diagnostic procedures. It is intended to replace fluoroscopic images formerly obtained through image intensifier technology. Not intended for mammography applications.

Technological Characteristics:

The Liebel-Flarsheim Direct Digital Imaging System is a modified version of the Hydra Vision Urological X-Ray System. The Liebel-Flarsheim Direct Digital Imaging System incorporates a solid state detector instead of an x-ray image intensifier like the predicate Hydra Vision Urological X-Ray System. The Liebel-Flarsheim Direct Digital Imaging System utilizes the same solid state detector as found in the UROSKOP Omnia (K101491) and the Nexus DRF Digital X-ray Imaging System (K103416). The imaging chain is the same as found on the Nexus DRF Digital X-ray Imaging System (K103416). Many of the same components found on the Liebel-Flarsheim Direct Digital Imaging System are used on the Hydra Vision Urological X-Ray System or include minor modifications to existing components.

General Safety and Effectiveness Testing and Conformance

Electrical, mechanical safety and performance testing according to standards IEC 60601-1 (1988 + A1:1991 + A2:1995), IEC 60601-1-1 (2000), IEC 60601-1-3, and IEC 60601-2-32 (1994). The device was also tested in accordance with standard IEC 60601-1-2 3rd edition 2007 – 03 for Electromagnetic Compatibility. All tests were satisfactory.

Performance Data:

Extensive functional testing was performed comparing the Liebel-Flarsheim Direct Digital Imaging System to the Hydra Vision Urological X-Ray System. These tests included evaluations of the contrast resolution, maximum entrance exposure, maximum viewable image, and motion imaging performance. The testing confirms the Liebel-Flarsheim Direct Digital Imaging System meets the required specifications and supports the claim of substantial equivalence. No adverse affects have been detected.

Conclusion:

The Liebel-Flarsheim Direct Digital Imaging System has the same intended use as its predicates. The imaging chain has been modified to include a flat panel detector and the Nexus DRF Digital X-ray Imaging System.

The results of all testing contained in this submission demonstrates the Liebel-Flarsheim Direct Digital Imaging System does not raise any new significant issues of safety, effectiveness or

performance when compared to the existing predicate devices. Liebel-Flarsheim Company LLC believes the Liebel-Flarsheim Direct Digital Imaging System is substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Liebel-Flarsheim Company LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 11 2012

Re: K121838
Trade/Device Name: Liebel-Flarsheim Direct Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 21, 2012
Received: June 22, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 3: Indications For Use Statement

510(k) Number (if known): K121838

Device Name: Liebel-Flarsheim Direct Digital Imaging System
Model Numbers: 700559 and 700560

Indications for Use:

The Liebel-Flarsheim Direct Digital Imaging System is a solid state detector X-ray system that facilitates digital radiologic and/or fluoroscopic procedures requiring a beam of diagnostic quality radiation and a flat imaging table primarily for urological applications such as functional x-ray diagnostics, endourology and minimal invasive urology/surgery. The system may be used for urological, gastroenterological, and gynecological treatment, planning and diagnostic procedures. It is intended to replace fluoroscopic images formerly obtained through image intensifier technology. Not intended for mammography applications.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121838